Sixty-Seventh Meeting of the

Obstetrics and Gynecology Devices Panel

Monday & Tuesday, June 9 & 10, 2003
Hilton DC North, Gaithersburg, Maryland

Microsulis Microwave Endometrial Ablation (MEA™) System (P020031)

DRAFT Discussion Questions

Safety and Effectiveness

1. Using an intent-to-treat analysis, the following represent the pivotal study results:

	MEA™	REA
Success Rate	87% (187/215)	83.2% (89/107)
Amenorrhea Rate	55.3% (119/215)	45.8% (49/107)

   Does the panel agree that these results demonstrate the clinical effectiveness of the MEA™ System?

2. Does the Panel agree with the sponsor's analysis of the 27 cases of serious adverse events that occurred with the MEA system in commercial use outside of the US? In particular, regarding the serious injuries that occurred with uterine perforation, does the Panel agree that these cases were the result of relative thinning of the uterine wall (due to trauma or surgical history), inappropriate pre-treatment, and failure to follow the Instructions for Use?

3. In commercial use (outside the U.S.), this device has been associated with transmural full thickness burns. Microsulis has provided their analysis of the injuries and the contributing factors. The company has also provided an analysis of the changes made to the commercial labeling and training to minimize this risk, for example:

   a. requirement for proctoring for new users;
   b. no mechanical D&C;
   c. use of ultrasound on all patients to determine uterine wall thickness; and
   d. perform hysteroscopy on all patients after cervical dilation and prior to insertion of the MEA™ applicator to confirm that the uterine cavity is intact.

   The training and labeling items identified in items a-d were included in the pivotal trial (n=215) without report of serious adverse event. (Many of these items were also practiced at three commercial centers (n=1400) without report of serious adverse event and over 2,400 consecutive patients have been treated worldwide without report of incident since November 2002.)

   Given the detailed information on the serious adverse events observed in past commercial use and the sponsor's analysis of the contributing factors, does the panel believe that the measures taken by the sponsor to improve the training and labeling will sufficiently reduce or eliminate the risk of full thickness burns?

4. The sponsor is proposing a minimum uterine thickness of 10 mm as measured by ultrasound. Microsulis believes that the maximum depth of tissue destruction with the MEA System is 7 mm. What does the panel consider to be a reasonable minimal uterine wall thickness to prevent full thickness burns considering:

a. the variability in uterine perfusion among the treatment population and the associated impact on depth of penetration
b. the uncertainty of the temperature at which thermal damage occurs; and
c. the imprecision in ultrasound measurements.

5. Does the panel agree with the instructions provided in the labeling for an ultrasound evaluation in 3-views?

    a. Are the instructions adequate for performance of 3-view pre-operative ultrasound?
    b. What is the appropriate level of training and/or experience necessary for the person performing the ultrasound evaluation?
    c. What is the appropriate timing for the ultrasound evaluation?

6. As with any endometrial ablation system, operation in the presence of a uterine perforation is associated with significant morbidity. The *intra-operative* safety features included as part of the MEA procedure for detecting a uterine perforation include:

    a. hysteroscopy after cervical dilation but prior to insertion of the MEA™ applicator;
    b. comparison of length of applicator to uterine sound measurement; and
    c. software feature (temperature rise gate (TRG)) that detects placement of the applicator outside of the uterine cavity at the initiation of treatment.

    Are these methods sufficient for identifying a uterine perforation prior to treatment?

<u>Labeling & Training</u>

7. Does the panel have any comments on the labeling and training provided by the sponsor? Are there specific recommendations related to the proposed:

    a. Indications;
    b. Contraindications;
    c. Warnings; and
    d. Precautions?

<u>Post-market Study</u>

8. Under current FDA guidance, patients from the pivotal study are scheduled to be followed for a total of 3 years after the procedure (1 year pre-market and 2-years post-market). If the panel votes to recommend approval of the MEA™ System, is there a need for additional post-approval studies? If so, what is the purpose of such studies and what are the key elements of the study design?

    Note: Post-approval studies may provide additional information about an approved device; however, the safety and effectiveness must be demonstrated before approval. The results of a post-approval study should not be expected to change the "approval" status of the device.